

Balancing Explicit Analysis and Deliberation in Decision Making

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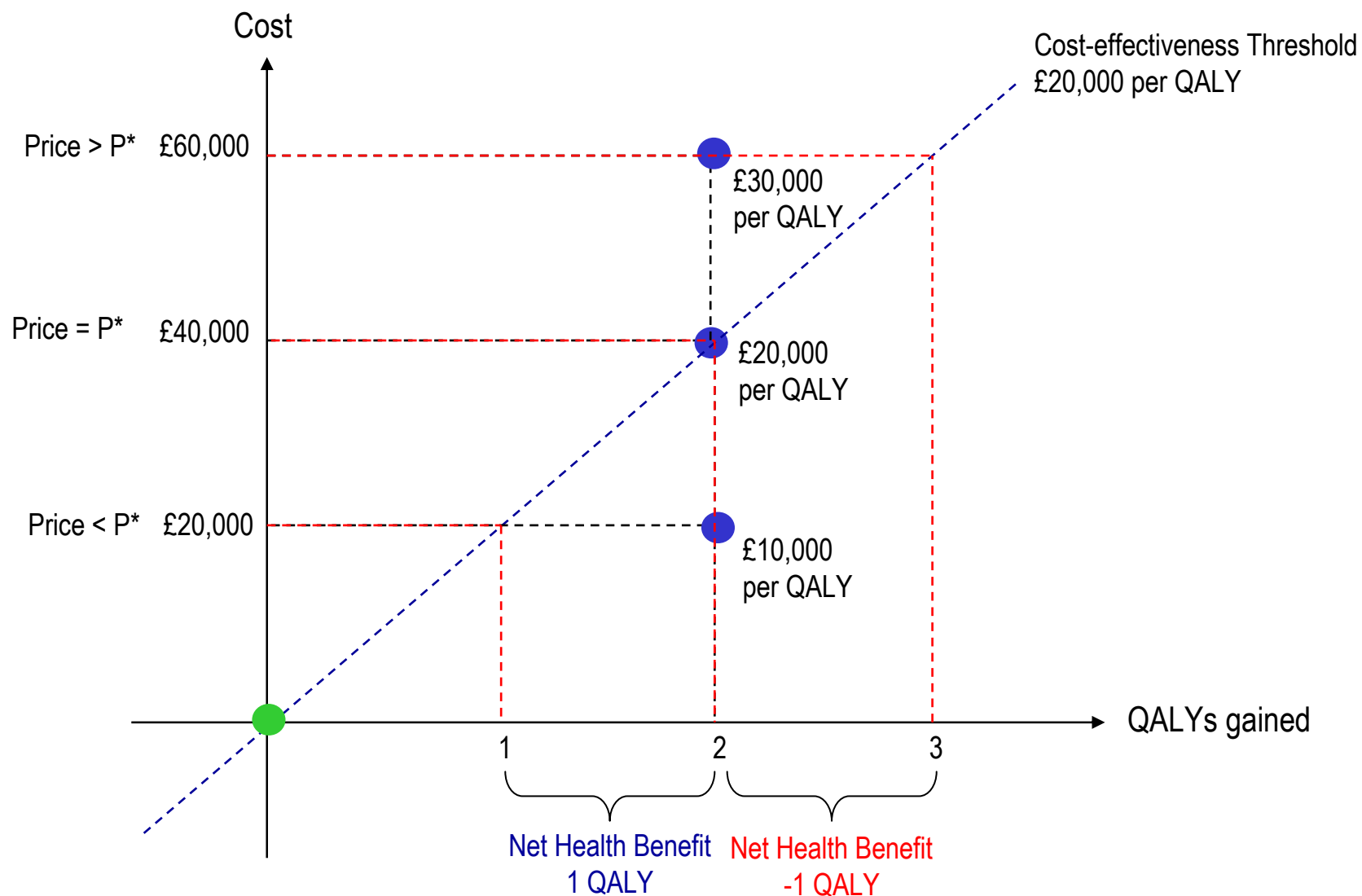
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Starting points and questions posed

- Health care systems with fixed budgets need to make resource allocation decisions
- Population health gain will be a key objective
- Any new (more expensive) technology will impose opportunity costs
- What is the appropriate analytical framework to inform decisions regarding the value of a new technology?
- What metric for health should be employed?
- How should other factors (e.g. interpersonal comparisons of health gain) be reflected in decisions and how?

Cost-effectiveness at NICE



What should the health metric look like?

- Need to be generic
 - Decisions across diseases and clinical specialties
 - Need to be able to compare health gain with health opportunity costs
- Unclear role for disease-specific measures of health
 - Unless ring-fenced budgets
 - No effects of technologies outside the disease of interest
- Needs to combine key dimensions of health
 - Length of life
 - Health-related quality of life

Why the QALY as a generic measure of individual health?

- Some empirical work to suggest QALYs imperfectly reflect individual preferences
- Little empirical work in the context of HTA informing real decisions
- Alternative measures developed but rarely applied (e.g. healthy-year equivalent)
- QALY legitimate to inform decisions
 - Widely used in empirical studies
 - Is (or should be) transparent
 - Strengths and weaknesses understood
 - Experience in alternative formal measures limited
 - Further research essential

Interpersonal comparisons of health gain

- Severity of baseline prognosis
- Lifetime health experience
- Non health-related disadvantage
- End of life
- Degree of 'blame'

"A QALY is a QALY is a QALY"

Those that gain health

Generally known

Those that lose health

Generally unknown

Inter-personal comparison of health

The analytic approach

- Concept of an 'equity weighted' QALY or a measure of the social value of health
- Literature exists
 - Methods of elicitation
 - Surveys of public preferences
 - Methods to augment/replace QALYs
- Limited use in applied studies
- What characteristics of individuals should be taken into account and who should select these?
- How should these characteristics be weighted/valued and by whom?

Inter-personal comparison of health

The deliberative approach approach

- Unweighted QALY gains in analysis do not mean these remain unweighted in decision making
- Range of factors which could be taken into account other than ICER versus
 - Inadequacy of QALY
 - Characteristics of gainers and losers
 - Innovative nature of the product
 - Sufficiency of evidence

What does 'taking into account' in decision making mean?

The gain in QALYs does not reflect all the drug's benefits

Extra weight is put on the health gain because of the characteristics of the recipients

The innovative nature of the product gives it extra value

On average, QALYs (from displaced services) are an accurate representation of opportunity cost

The characteristics of the recipients given health gain more important than the characteristics of those who, on average, lose health

It is reasonable for population health to fall today in the anticipation of future health gain

NICE's deliberations at appraisal

6.2.23 Above a most plausible ICER of £20,000 per QALY gained, judgements about the acceptability of the technology as an effective use of NHS resources will specifically take account of the following factors.

- The degree of certainty around the ICER. In particular, the Committee will be more cautious about recommending a technology when they are less certain about the ICERs presented.
- Whether there are strong reasons to indicate that the assessment of the change in HRQL has been inadequately captured, and may therefore misrepresent the health utility gained.
- The innovative nature of the technology, specifically if the innovation adds demonstrable and distinctive benefits of a substantial nature which may not have been adequately captured in the QALY measure.

2004 – “the particular features of the condition and population receiving the technology”

NICE. *Guide to the Methods of Technology Appraisal*. London: NICE, 2008.

NICE's Citizens' Council and severity

... NICE and its advisory bodies should indeed take the severity of a disease into account when making decisions

... there was unanimity that rather than do so by including severity in the calculation of the QALY, it should be taken “into consideration” alongside the cost and clinical effectiveness evidence.

NICE Citizens' Council. *Quality Adjusted Life Years (QALYs) and the severity of illness*, 2008 (www.nice.org.uk)

Hot off the press...

2 Criteria for appraisal of end of life medicines

- 2.1 The Institute will amend the advice it gives to its Appraisal Committees to ask them to consider recommending the use of medicines, with an incremental cost effectiveness ratio in excess of £30,000, where all the following criteria are met:
 - 2.1.1 The medicine is indicated, in its licence, for a patient population normally not exceeding 7000 new patients per annum, and;
 - 2.1.2 The medicine is indicated for the treatment of patients with a diagnosis of a terminal illness and who are not, on average, expected to live for more than 24 months, and;
 - 2.1.3 There is sufficient evidence to indicate that the medicine offers a substantial extension to life, compared to current NHS treatment.

NICE. Appraising end of life medicines, 2008.

<http://www.nice.org.uk/newsevents/infocus/EndOfLifeMedicinesConsultation.jsp>

Balancing analysis with deliberation in decision making

- Analytical approaches provide explicit means of linking evidence and scientific and social value judgements with decisions
- Analytical approaches may hinder decision making when they are not fully developed and understood
- Need ongoing emphasise of methods development
- Deliberation in decision making will remain
- Decision makers need to understand the implications of their decisions:
 - What particular ‘considerations’ mean in principle
 - Best estimates implications for population health